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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,926	02/06/2001	John Collinge	102286-408CON	8540

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 12/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/778,926	Collinge
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later then three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 1, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10, 13-16, 26, and 28-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10, 13-16, 26, and 28-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Amendment

1. Applicant has canceled claim 27. Claims 1-3, Claims 4-10, 15, 16, and 26 have been amended and new claims 28-32 have been added. Therefore, claims 1-10, 13-16, 26, and 28-32 are pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 2 are rejected under 35 U.S.C. 103 (a) over Harrington et al. (U.S Patent 4,892,814) (January 9, 1990) in view of Prusiner et al. (PCT International Publication Number WO 95/31466) (November 23, 1995).

Harrington et al teach a method for typing a sample of a prion or spongiform encephalopathy disease or Creutzfeldt-Jakob disease, the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Abstract and TABLE 1 and Column 3, line 63 to column 6, line 8).

Harrington et al teach a method for assessing and predicting the susceptibility of a human to bovine spongiform encephalopathy or a derivative thereof. (Abstract and Table 1).

Harrington et al do not teach the sizes and ratios of distinct PrP Sc type glycoforms.

Prusiner et al. teach the sizes and ratios of distinct PrP Sc type glycoforms (Page 2, lines 3-6 and Examples 8-9).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the sizes and ratios of distinct PrP Sc type glycoforms of Prusiner et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Harrington et al. since Prusiner et al. state, "It appears that the scrapie isoform of the prion protein (PrPSc) is necessary for both the transmission and pathogenesis of the transmissible neurodegenerative diseases of animals and humans (Page 2, lines 3-6)". An ordinary practitioner would have been motivated to substitute and combine the sizes and ratios of distinct PrP Sc type glycoforms of Prusiner et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Harrington et al. in order to achieve the express advantages, as noted by Prusiner et al., of a scrapie isoform of the prion protein (PrPSc) which is necessary for both the transmission and pathogenesis of the transmissible neurodegenerative diseases of animals and humans.

4. Claims 1, 3-10, 13-16, 26, and 28-32 are rejected under 35 U.S.C. 103(a) as being over Race et al. (American Journal of Veterinary Research, (June, 1992), Vol. 53 (6), pages 883-889) in view of Prusiner et al. (PCT International Publication Number WO 95/31466) (November 23, 1995).

Race et al teach a method for typing a sample of a prion or spongiform encephalopathy disease. the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Summary, Introduction and TABLE 1 and Figures 1-5).

Race et al teach a method wherein the comparison of physicochemical properties comprises a comparison of protease resistance (Summary, Introduction and TABLE 1 and Figures 1-5).

Race et al teach a method for identifying infection in an animal and tissue of bovine spongiform encephalopathy the method comprising isolating a prion protein from the animal and/or tissue and identifying that the prion protein can be characterized by having three distinct bands on an electrophoresis gel following proteinase K digestion (MATERIALS AND METHODS SECTION, Tissue Preparation for Immunoblot Analysis Subsection, Page 884, column 1, lines 16-47), the bands comprising I) a band of highest molecular weight in the greatest proportion, ii) a band of lowest molecular weight in the lowest proportion, and iii) a band with a molecular weight between I and ii and of a proportion between I and ii. (Figure 1, lanes 4-6 and Lanes 8,10 and 11 of Figure 5).

Race et al teach a method wherein the animal is mammalian and non-bovine (Summary).

Race et al teach a method for identifying infection in an animal and/or tissue (Results Section, Analysis of sheep brain Subsection and Figures 1 and 5).

Race et al do not teach the sizes and ratios of distinct PrP Sc type glycoforms.

Prusiner et al. teach the sizes and ratios of distinct PrP Sc type glycoforms (Page 2, lines 3-6 and Examples 8-9).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the sizes and ratios of distinct PrP Sc type glycoforms of Prusiner et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Race et al. since Prusiner et al. state, "It appears that the scrapie isoform of the prion protein (PrPSc) is necessary for both the transmission and pathogenesis of the transmissible neurodegenerative diseases of animals and humans (Page 2, lines 3-6)". An ordinary practitioner would have been motivated to substitute and combine the sizes and ratios of distinct PrP Sc type glycoforms of Prusiner et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Race et al. in order to achieve the express advantages, as noted by Prusiner et al., of a scrapie isoform of the prion protein (PrPSc) which is necessary for both the transmission and pathogenesis of the transmissible neurodegenerative diseases of animals and humans.

Response to Amendment

5. In response to amendment, all previous rejections including 112 (second paragraph), improper multiple dependency, and 102 rejections are hereby withdrawn. However, two new 103(a) rejections have been included.

Response to Arguments

6. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703)605-1237.

Arun Chakrabarti,

Patent Examiner,

December 19, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600